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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,987	03/13/2001	Christian Waeber	M0765/7035 (ERG/MAT)	9309

7590 07/16/2002  
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Boston, MA 02210-2211

EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/804,987

Applicant(s)

WAEBER ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12,23,34,43,56,66,67,69,70 and 78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12,23,34,43,56,66-69 and 77 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12 and 23, drawn to a method for treating a subject having, or at risk of having, a disorder which can be treated by increased vasoconstriction or inhibition of vasodilation, classified in class 514, subclass 2.
- II. Claims 34, 43, and 56, drawn to a method for treating a subject having, or at risk of having, a disorder which can be treated by increased vasodilation or inhibition of vasoconstriction, classified in class 514, subclass 2.
- III. Claim 66, drawn to a method for identifying an agent that regulates vasoconstriction, comprising selecting an agent that binds to sphingosine kinase, classified in class 435, subclass 7.1.
- IV. Claim 67, drawn to a method for identifying an agent that regulates vasoconstriction, comprising selecting an agent that binds to an EDG receptor, classified in class 435, subclass 7.1.
- V. Claim 68, drawn to a method for identifying an agent that regulates vasoconstriction, comprising selecting an agent that binds to a sphingosine-1-phosphate phosphatase, classified in class 435, subclass 7.1.
- VI. Claim 69, drawn to a pharmaceutical preparation comprising an agent that up-regulates EDG receptor signaling, classification depends upon the structure of the agent.

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VII. Claim 77, drawn to a pharmaceutical preparation comprising an agent that down-regulates EDG receptor signaling, classification depends upon the structure of the agent.

2. The inventions are distinct, each from the other for the following reasons. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case, the two inventions are drawn to two methods for treating subjects having opposite disorders: one disorder can be treated by increased vasoconstriction/inhibition of vasodilation; the other disorder can be treated by increased vasodilation/inhibition of vasoconstriction. Thus, the methods are exclusive and require non-cohesive searches and considerations.
3. Inventions III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case, the different inventions are drawn to completely different methods for identifying agents that regulate vasoconstriction. Invention III comprises selecting an agent that binds to sphingosine kinase, Invention IV comprises selecting an agent that binds to an EDG receptor, whereas Invention V comprises selecting an agent that binds to a sphingosine-1-phosphate phosphatase. Thus, the three methods are not interchangeable and require non-cohesive searches and considerations.

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4. Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case, the different inventions are drawn to completely different pharmaceutical preparations that have an opposite effect on EDG receptor signaling. Thus, the two compositions are not interchangeable and require non-cohesive searches and considerations.
5. Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instant case, an agent that up-regulates EDG receptor signaling may be used in a materially different process such as to study EDG receptor-elicited signal transduction. For the same reason, Inventions II and VII are related but distinct inventions.
6. Invention I is an independent invention from Inventions VII; Invention II is an independent invention from Invention VI. The different inventions are drawn to distinct product and method inventions.
7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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8. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for any other group, restriction for examination purposes as indicated is proper.
9. Groups I and VI contain claims directed to patentably distinct species of agents that up-regulate EDG receptor signaling. The species are: (i) a sphingosine kinase activator; (ii) an EDG receptor agonist; (iii) a sphingosine-1-phosphate phosphatase inhibitor.

Should applicants elect Group I (or Group VI) and an EDG receptor agonist as the agent, applicants are further required under 35 U.S.C. 121 to elect a single species of EDG receptor agonists recited in claims 5-8 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li  
Examiner  
July 10, 2002

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
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